DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 18, 2015

L&K BIOMED Co., Ltd
Ms. Yerim An
RA Specialist
#201, 202 16-25, Dongaekjungang-ro 16 beon-gil
Giheung-gu, Yongin-si
Gyeonggi-do, 446-916
Republic of Korea

Re: K151140
Trade/Device Name: LnK Lumbar Interbody Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 17, 2015
Received: July 20, 2015

Dear Ms. An:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K151140
Device Name: LnK Lumbar Interbody Fusion Cage System

Indications For Use:

LnK Lumbar Interbody Fusion Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. LnK Lumbar Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CER801 Subpart D) (21 CER801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OED)

510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. Submitter:

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Contact Person: Yerim An

Date prepared: Aug, 13, 2015

2. Device Identification

Trade Name	LnK Lumbar Interbody Fusion Cage System
Common Name	Intervertebral Body Fusion Device
Product Code	MAX
Classification Name	Intervertebral body fusion device (888.3080)

3. Predicate or legally marketed devices which are substantially equivalent

The design feature and indications for use for the subject LnK Lumbar Interbody Fusion Cage System is substantially equivalent to the following predicates:

- Primary Predicate: LnK Lumbar Interbody Fusion Cage System_ L&K BIOMED Co., Ltd (K121096)
- Additional Predicate: LnK Lumbar Interbody Fusion Cage System_ L&K BIOMED Co., Ltd (K110783)

4. Description of the Device

The LnK Lumbar Interbody Fusion Cage System is intervertebral body fixation devices intended for use as an aid in spinal fixation. This system is fabricated and manufactured from PEEK-OPTIMA® LTl as described by ASTM F2026. The Tantalum marker used for this product is made to the voluntary standard of ASTM F560. The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates. LnK Lumbar Interbody Fusion Cage System Implants

are supplied as sterile or non-sterile.

The LnK PLIF PEEK Cages are to be implanted via posterior approach. These devices are placed two implants on each side of the interbody space (right and left).

The LnK T-PLIF PEEK Cages which is used in transforaminal posterior lumbar interbody fusion technique. However, this kind of cage is to be implanted only one implant on interbody space.

The LnK TLIF PEEK Cages are a “banana” shaped. Implants are dedicated to transforaminal approach. TLIF technique involves placing only one bone graft spacer in the middle of the interbody space, without retraction of the spinal nerves.

The LnK ALIF PEEK Cages are to be implanted via anterior approach.

The LnK DLIF PEEK Cages are to be implanted via direct lateral interbody fusion approach. LnK DLIF PEEK Cage can be used in an open approach and a percutaneous approach with MIS instrumentation.

5. Indication for use

LnK Lumbar Interbody Fusion Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. LnK Lumbar Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. Comparison of the technology characteristics of the device to predicate and legally marketed devices

No	Item	LnK Lumbar Interbody Fusion Cage System	LnK Lumbar Interbody Fusion Cage System (Predicate)
1	Manufacturer	L&K BIOMED Co., Ltd.	L&K BIOMED Co., Ltd.
2	Material	PEEK and Tantalum	PEEK and Tantalum
3	510(K) Number		K121096
4	Product Code	MAX	MAX
5	Class	ClassII	ClassII
6	Intended Use	LnK Lumbar Interbody Fusion Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. LnK Lumbar Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.	LnK Lumbar Interbody Fusion Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. LnK Lumbar Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

7. Performance Data

Mechanical performance of additional components is same with predicated (K121096). Additional sizes are not worst case. Therefore, We substitute mechanical test data of additional components of LnK Lumbar Interbody Fusion Cage System with it of LnK Lumbar Interbody Fusion Cage System(K121096).

The LnK Lumbar Interbody Fusion Cage System was tested according to the ASTM F 2077, specifically, Static and Dynamic Axial Compression, Static and Dynamic Compression-Shear Testing, Static and Dynamic Torsion Testing, Expulsion Testing and Static Subsidence testing under Axial Compression, per ASTM F 2267.

8. Conclusion

The additional components of LnK Lumbar Interbody Fusion Cage System are substantially equivalent to the device.